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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/586,594	01/16/1996	JEFFREY M. FRIEDMAN	600-1-162	3635

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EXAMINER

O HARA, EILEEN B

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/586,594

Applicant(s)

FRIEDMAN ET AL.

Examiner

Eileen O'Hara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-5, 7-9, 63, 66 and 68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-5, 7, 8, 63, 66 and 68 is/are rejected.
- 7) ☒ Claim(s) 9 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 January 1996 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

1. Claims 3-5, 7-9, 63, 66 and 68 are pending in the instant application. Claims 3-5, 7, 8, 66 and 68 have been amended and claims 6, 14-62, 64, 65 and 67 have been canceled and claims as requested by Applicant in the Paper filed #, 2004.

All claims are currently under examination.

Withdrawn Objections and Rejections

2. Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

New Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 3, 4 and 66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3.1 Claims 3 and 4 are indefinite because they encompass a leptin receptor which is encoded by a nucleic acid which is identifiable with a polymerase chain reaction. Defining a protein as being encoded by a nucleic acid that is "identifiable" under non-specified circumstances does not clearly set forth the metes and bounds of the patent protection desired.

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3.2 Claim 66 is indefinite because it encompasses a body appearance improving composition for modulating the body weight of an individual comprising a soluble leptin receptor, and it is not clear how body weight would be modulated by this compound, up or down. Applicants amended the claim to recite “modulating” instead of “reducing”, so that it encompasses both weight gain or weight loss, and asserted on page 6 of the response that a soluble receptor could also be expected to result in weight loss, particularly in that binding circulating in an individual expressing a mutant leptin causing weight gain could block the weight gain. However, the Examiner is not aware of any mutant leptin that could cause weight gain.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 3 and 4 are rejected under 35 U.S.C. 102(e) as being anticipated by Tartaglia et al., US Patent No. 6,506,877, filing date Dec. 28, 1995.

Claims 3 and 4 encompass a isolated leptin receptor which is a soluble receptor and which is encoded by a nucleic acid which is identifiable with a PCR probe selected from a probe for clone seven and a probe for clone 11, or probe for clone S14 and probe for clone S3.

Tartaglia et al. discloses a protein (SEQ ID NO: 2) that is 100% identical to amino acids 1-796 of SEQ ID NO: 10 of the instant invention, which is the soluble portion of the protein, and

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nucleic acid of SEQ ID NO: 1 that encodes the protein. The nucleic acid of Tartaglia et al. is 100% identical to nucleotides 1-2432 of SEQ ID NO: 9 of the instant invention, which encodes amino acids 1-796 of SEQ ID NO: 10. Probes to clones 7, 11, S14 and S3 recognize the extracellular region of the protein of SEQ ID NO: 10, and therefore, these probes would also recognize the same region of the nucleic acid of Tartaglia and therefore the protein of Tartaglia would be identifiable with those probes. Therefore, Tartaglia et al. anticipates the claims.

Maintained Objections and Rejections

Claim Objections

5. Claim 9 remains objected to because of the following informalities: it encompass non-elected inventions, which should be deleted. Sections b) and c) encompass the non-elected inventions. If the claim is amended to delete the non-elected inventions, it should be noted that "selected from the group consisting of a)" should also be deleted.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 3-5, 7, 8, 63, 66 and 68 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

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reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants traverse the rejection on page 6 of the response, and assert that Applicants have described and provided the specific DNA a protein sequence for soluble receptor species OB-Re (SEQ ID NO: 10), as well as the truncated variant of amino acids 28-805 of SEQ ID NO: 10, which was isolated as a naturally occurring soluble receptor species, using procedures and methods detailed in the specification. Applicants assert that the skilled artisan could readily, without undue experimentation, isolate additional species of the genus of such soluble receptors, including additional and related allelic variants thereof.

Applicants' arguments have been fully considered but are not deemed persuasive. The issue is not undue experimentation to isolate additional species, but that of written description. An adequate written description of a DNA (or encoded polypeptide), "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id at 1170, 25 USPQ2d at 1606."

Therefore, the rejection is maintained.

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 8, 63, 66 and 68 remain rejected under 35 U.S.C. 102(e) as being anticipated by Tartaglia et al., US Patent No. 6,506,877, filing date Dec. 28, 1995.

Applicants traverse the rejection on pages 6-7 of the response and assert that Tartaglia et al. does not anticipate the soluble leptin receptor of the instant invention as claimed by Applicants, cite *PPG Industries, Inc. vs Guardian Industries Corp.*, and assert that Tartaglia et al. neither discloses every element of the rejected claims nor enables one skilled in the art to make the anticipating subject matter. Applicants point to column 6 of Tartaglia in which the extracellular domain is from about amino acid residues 23-837, and assert that Tartaglia et al. does not teach, anticipate or even suggest the soluble receptor OB-Re of SEQ ID NO: 10 of the instant invention having an end at amino acid His⁷⁹⁶.

Applicants' arguments have been fully considered but are not deemed persuasive. Because claim 8 is so broadly written and does not require any sequence, Tartaglia et al. anticipates the claims. Claim 8 recites "A isolated leptin receptor (OB-R) polypeptide which is a soluble receptor." There is no recitation of structure. Tartaglia et al. teaches an isolated leptin receptor (OB-R) polypeptide which is a soluble receptor. The additional, divergent sequence after His⁷⁹⁶ are not relevant. Additionally, Tartaglia et al. teach that truncations of specific functional domains can be made. At column 7, lines 61-67, Tartaglia et al. states:

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“In particular, the invention described in the subsections below encompasses ObR, polypeptides or **peptides corresponding to functional domains of the ObR (e.g., ECD, TM or CD)**, mutated, **truncated** or deleted ObRs (e.g. an ObR with one or more functional domains or portions thereof deleted, such as .DELTA.TM and/or .DELTA.CD),”

Therefore, Tartaglia et al. anticipates the claims, and the rejection is maintained.

It is believed that all pertinent arguments have been answered.

Conclusion

8.1 Claims 3-5, 7, 8, 63, 66 and 68 are rejected.

8.2 Claim 9 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form, and if non-elected inventions were deleted from the claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (571) 272-0878. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached at (571) 272-0961.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://portal.uspto.gov/external/portal/pair>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Eileen B. O'Hara, Ph.D.

Patent Examiner

A handwritten signature in cursive script that reads "Eileen B. O'Hara".

EILEEN B. OHARA
PATENT EXAMINER